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Patent Application

Inventors: David Feygin et al.

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Title: Vascular-Access Simulation System with Ergonomic Features

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

APPEAL BRIEF UNDER 37 CFR 41.67

Pursuant to 37 CFR 41.67, this brief is filed in support of the appeal in this application.

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REAL PARTY IN INTEREST

The real party of interest in this application is the assignee of this application, which is Laerdal.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

This case was originally filed with claims 1-40. Claims 2-3, 8-12, 20, 26-27, and 29-32 have been canceled; claims 1, 4-7, 13-19, 21-25, 28, and 33-40 are pending. Each of the pending claims stand rejected. All of the rejected claims are being appealed.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the most recent Official Action, which is dated October 6, 2008.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The claims on appeal relate to a simulator for practicing vascular-access procedures, such as inserting a needle and/or catheter into a vein. The simulator enables a user to practice the procedures without subjecting a human subject to the inevitable discomfort that accompanies such procedures.

In the illustrative embodiment, vascular-access simulator (100) includes haptics device (102) and data-processing system (104). *See* FIG. 1.

The term "haptics," as in "haptics device (102)," relates to touch; in particular, the sense of touch. A fundamental function of haptics device (102), and indeed any haptics interface, is to create a means for communication between human users and machines. This "communication" is possible since humans are capable of "mechanically" interfacing with their surroundings due, at least in part, to a sense of touch. Thus, haptics device (102) is the physical interface for performing simulated vascular-access procedures.

The design of simulator (100) proceeded from the inventors' understanding that the more realistic the simulation, the more useful the training experience is likely to be. To that end, simulator (100) includes mechanisms that enable a user to practice certain skin-interaction procedures (*i.e.*, palpation, occlusion and skin stretch) that normally accompany a vascular access procedure. These techniques variously enable a practitioner to locate a vein in preparation for needle/catheter insertion and are also intended to reduce patient discomfort.

In the Background section of appellant's patent application (and in an Information Disclosure Statement), U.S. Pat. No. 6,470,302 to Cunningham *et al.* was disclosed. That patent discloses a vascular-access simulation system and is particularly relevant to appellant's claimed simulation system. The simulator disclosed in that patent was commercially available. In fact, in developing their claimed simulator, the inventors studied that prior-art simulator. The inventors identified many shortcomings of the system that is disclosed in the '302 patent; shortcomings that they sought to avoid in development of claimed simulation system. Some of the shortcomings pertain to the ergonomics of the '302 system, which are a focus of the claims on appeal.

In particular, the various mechanisms of the claimed apparatus are configured so that one or more of the following conditions are met:

- The profile of the haptics device remains relatively low — advantageously not substantiallly higher than a person's arm when it is resting flat on a surface.
- The shape of the haptics device is not overtly inconsistent with human anatomy (*e.g.*, an arm, *etc.*).
- When practicing a vascular-access procedure using the haptics device, the position of a user's hands is similar to the position of the hands when performing an actual vascular-access procedure.
- The sites at which the palpation and skin stretch techniques are performed are correct relative to one another (in terms of the sites of these techniques during an actual vascular-access procedure).
- The sites at which the occlusion and skin stretch techniques are performed are correct relative to one another (in terms of the sites of these techniques during an actual vascular-access procedure).
- The sites at which the occlusion and skin stretch techniques are performed are correct relative to the site at which the catheter/needle is inserted into the haptics device (in terms of the sites of these techniques during an actual vascular-access procedure).
- The various mechanisms of the haptics device are beneath the "skin" of the haptics device.

The independent claims 1, 25, and 35 on appeal are presented below and mapped to the specification by page and line number and to the drawings, as applicable.

Claim 1 recites an apparatus comprising:

> pseudo skin;
>
> a receiver, wherein said receiver receives an end effector through an insertion region in said pseudo skin; and
>
> a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein:
>
> (a) said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin; and
>
> (b) said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.

Pseudo skin: identified by call out "220," is first referenced at paragraph [0038]; *see also* paragraphs [0026]-[0029], [0040]-[0043], FIGs. 2, 7, *etc*.

Receiver: identified by call out "226," is first referenced at paragraph [0038]; *see also* paragraphs [0045]-[0046], *etc*., FIGs. 4, 7, *etc*.

End effector: identified by call out "218," is first referenced at paragraph [0038]; *see also* paragraphs [0039], [0044]-[0046], *etc*., FIGs. 2, 3, 8, *etc*.

Insertion Region: identified by call out "334," is first referenced at paragraph [0041]; *see also* [0044] and FIG. 3.

First device for performing a first skin interaction technique … palpation or occlusion: Palpation module identified by call out "222," is first referenced at paragraph [0038]; *see also* paragraphs [0042]-[0043], [0054], [0058], *etc*., FIGs. 2, 4, 5, 7.

First skin-interaction region of the pseudo skin: identified by call out "331," is first referenced at paragraph [0041]; *see also* paragraph [0057], FIG. 3.

Claim 25 recites an apparatus comprising:

> a housing, wherein said housing has an opening in an uppermost surface thereof;
>
> pseudo skin, wherein said pseudo skin covers said opening;
>
> an end effector, wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure;
>
> and a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin, and wherein said plurality of mechanisms include:
>
> (a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin; and
>
> (b) a second mechanism for receiving said end effector.

Housing: identified by call out "216," is first referenced at paragraph [0039]; *see also* pararagraphs [0041], [0043], [0053]-[0065], FIGs. 2 and 3.

Opening: identified by call out "330" or "332," is first referenced at paragraph [0041]; *see also*, [0043], [0044], [0056], [0057], FIG. 3.

Pseudo skin: identified by call out "220," is first referenced at paragraph [0038]; *see also* paragraphs [0026]-[0029], [0040]-[0043], FIGs. 2, 7, *etc*.

End effector: identified by call out "218," is first referenced at paragraph [0038]; *see also* paragraphs [0039], [0044]-[0046], *etc*., FIGs. 2, 3, 8, *etc*.

First mechanism…skin stretch technique: identified by call out "224," is first referenced at paragraph [0038]; *see also* paragraphs [0042], [0058]-[0060], *etc*., FIGs. 2, 4, 5, 7.

Second mechanism for receiving said end effector: identified by call out "226," is first referenced at paragraph [0038]; *see also* paragraphs [0045]-[0046], *etc*., FIGs. 4, 7, *etc*.

Claim 35 recites an apparatus comprising:

> a pseudo skin;
>
> a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, including at least one mechanism for performing a non-invasive skin-interaction technique that is performed on said pseudo skin, wherein said plurality of mechanisms are disposed under said pseudo skin and are covered by said pseudo skin; and
>
> a housing, wherein said housing contains said plurality of mechanisms.

Pseudo skin: identified by call out "220," is first referenced at paragraph [0038]; *see also* paragraphs [0026]-[0029], [0040]-[0043], FIGs. 2, 7, *etc*.

a plurality of mechanisms … for simulating a vascular-access procedure: includes mechanisms such as palpation module identified by call out "222", skin-stretch module identified by call out "224," and receiver (needle-stick module) identified by call out "226." For further mapping of these elements, see the discussion with respect to claim 1 for palpation module "222" and receiver "226" and the discussion with respect to claim 25 for skin-stretch module "224."

At least one mechanism for performing a non-invasive skin-interaction technique: includes mechanisms such as palpation module identified by call out "222" or skin-stretch module identified by call out "224." For further mapping of these elements, see the discussion with respect to claim 1 for palpation module "222" and the discussion with respect to claim 25 for skin-stretch module "224."

Housing: identified by call out "216," is first referenced at paragraph [0039]; *see also* pararagraphs [0041], [0043], [0053]-[0065], FIGs. 2 and 3.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Ground 1. Whether claims 1, 4-7, 13-19, 21-25, 28, and 33-40 were properly rejected under 35 USC §112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention.

Ground 2. Whether claims 1, 35, and 38-40 were properly rejected under 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,654,000 to Rosenberg in view of U.S. Pub. Pat. App. 2003/0031993 to Pugh.

Ground 3. Whether claims 4-7 and 13-24 were properly rejected under 35 USC 103(a) as being unpatentable over the combination of Rosenberg and Pugh, further in view of U.S. Pat. No. 6,470,302 to Cunningham *et al*.

Ground 4. Whether claim 25 was properly rejected under 35 USC 103(a) over Cunningham *et al*. in view of Rosenberg.

Ground 5. Whether claims 28 and 33 were properly rejected under 35 USC 103(a) over Cunningham *et al*. and Rosenberg, further in view of Pugh.

Ground 6. Whether claim 34 was properly rejected under 35 USC 103(a) over Cunningham *et al*. and Rosenberg, further in view of Pugh.

Ground 7. Whether claims 36 and 37 were properly rejected under 35 USC 103(a) as being unpatentable over Rosenberg.

ARGUMENTS

Ground 1. The Examiner alleges that claims 1, 4-7, 13-19, 21-25, 28, and 33-40 are indefinite under 35 USC §112, ¶2 for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention.

Independent claims 1, 25, and 35 recite devices/mechanisms than enable a user of the simulation system to perform certain "skin-interaction" techniques, such as palpation, occlusion, or skin stretch. The independent claims recite that these mechanism are disposed beneath and covered by a "pseudo skin." The Examiner alleges that she is "unsure" as to how these mechanisms can be used to perform a first skin-interaction technique on the skin if they are, in fact, disposed beneath the skin.

Appellant notes, as an initial matter, that the last *Official Action* issued by the Examiner marks the fifth time that she examined the appellant's claims. Although the claim language has been amended since the original filing, the originally-filed claims and all iterations since have included limitations pertaining to mechanisms, located beneath the pseudo skin of the device, for practicing skin-interaction techniques. Appellant does not understand how this rejection is first being raised on a fifth examination.

The claims on appeal do particularly point out and distinctly claim the subject matter that the appellant regards as its invention. The language of the claims accurately recites the location of the mechanisms relative to (1) other mechanisms in the device; and/or (2) the pseudo skin; and/or (3) to the housing. The language of the claims also accurately recites the locations on the pseudo skin at which user interacts with each mechanism relative to (1) other mechanisms; and/or (2) the housing; and/or (3) the user. And that is what this case is about—ergonomics, which, as previously noted, is an important consideration for a device that is intended as a training tool.

Paragraph [0001] of appellant's specification incorporates by reference four cases that pertain to other aspects of the simulator (100). (*See* appellant's amendment filed September 18, 2007 wherein attorney docket numbers were replaced by serial numbers.) Several of these incorporated cases go into extreme detail concerning the structure and use of the various internal mechanisms, including the palpation/occlusion module and skin stretch module. Any uncertainty about the functioning of these mechanisms can be resolved by reference to the incorporated references.

Even without reference to the related cases, one skilled in the art will know that to interact with the palpation mechanism (to practice simulated palpation or occlusion) or to interact with the skin stretch mechanism (to practice a simulated skin stretch technique) simply requires a user to touch his or her fingers to the pseudo skin at the appropriate sites and perform the technique as it would otherwise be performed on a patient. The mechanisms are disposed directly below the resilient skin such that they will function in accordance with their design to enable a user to practice the technique.

In view of the foregoing, it is believed that the Section 112 rejection of the pending claims is not sustainable and should be reversed.

***Ground* 2.** The Examiner alleges that claims 1, 35, and 38-40 are unpatentable under 35 USC 103(a) over U.S. Pat. No. 6,654,000 to Rosenberg in view of U.S. Pub. Pat. App. 2003/0031993 to Pugh.

Claim 1. Claim 1 recites an apparatus comprising:

> pseudo skin;
>
> a receiver, wherein said receiver receives an end effector through an insertion region in said pseudo skin; and
>
> a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein:
>
> (a) said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin; and
>
> (b) said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.

The Examiner alleges, at page 4 of her *Official Action*, that Rosenberg discloses:

(i) pseudo skin (barrier (22));
(ii) a receiver (trocar (24));
(iii) the receiver receives an end effector (lapraroscopic tool 18) through an insertion region in said pseudo skin;
(iv) a first device (mechanical apparatus (25)) for performing a first skin interaction technique;
(v) said receiver and said first device are disposed beneath said pseudo skin; and

(vi) said receiver and said first device are covered by said pseudo skin.

Appellant disagrees with at least allegations (iv)-(vi).

As to allegation (iv), according to Rosenberg, device (25) is a "gimbal apparatus" that "constrains an object that is engaged with the object receiving portion (44) [*see* FIG. 2] to four degrees of freedom." (Col. 7, lines 50-52.) Figures 3 through 5 depict the manner in which device (25) provides these four degrees of freedom. Figure 6 provides a simplified illustration of the four degrees of freedom. In particular, it shows three rotational degrees of freedom and one translational degree of freedom. In any event, the purpose of gimbal apparatus (25) is not to enable a practitioner to perform a skin interaction technique (which, in claim 1, is either "palpation" or "occlusion").

As to allegations (v) and (vi), neither the receiver (trocar (24)) nor the first device (apparatus (25)) are disposed *beneath* pseudo skin (barrier (22)) nor are they covered by it. As depicted in Fig. 1, trocar (24) and apparatus (25) are disposed on one side of barrier (22) and the user is disposed on the other side of it. These distinctions are important, as explained further below.

As noted in the Summary section of this Brief, the claims on appeal pertain to certain ergonomic considerations of the appellant's simulator. The following excerpt from the specification is taken from paragraphs [0054]-[0056]:

> It is the inventors' belief that, to the extent a user's interaction with haptics device **102** more closely tracks a practitioner's experience of performing the actual procedure (that the device is designed to simulate), the training experience is more useful. In this regard, the utility of a device such as haptics device **102** is enhanced by a design that is heavily influenced by form-function considerations and ergonomics. And, to that end, the illustrative embodiment of haptics device **102** has been strongly influenced by such considerations. In particular, and as described more fully below, considerations such as the positions of the functional modules (*e.g.*, modules **222**, **224**, **226**, *etc.*) relative to one another and relative to pseudo skin **220**, as well as the shape and dimensions of housing **216** have been taken into account in the design of haptics device **102**.
>
> Referring now to FIG. 3 …. housing **216** is subtly shaped like a portion of a human arm, yet is nondescript enough to avoid creating a discontinuity between what is seen and what is felt.

> Pseudo skin **220** is accessible through openings **330** and **332** to perform simulated skin interaction techniques and needle/catheter insertion. In the illustrative embodiment, pseudo skin **220** is disposed adjacent to the inside surface of housing **216** so that it appears to be nearly co-extensive (*i.e.*, co-planar) with housing **216** at openings **330** and **332**. This is intended to create a subtle suggestion that the surface of housing **216** is "skin" at regions other than where pseudo-skin **220** is accessed. Consistent with human anatomy, the remaining functional elements of haptics device **102** (elements **222** – **228**), with the exception of needle/catheter module **218**, are "hidden" beneath pseudo skin **220**.

As a consequence, the position/location/orientation of appellant's claimed "receiver" and "first device for performing a first skin interaction technique" relative to that of the claimed "pseudo skin" is important and, in fact, it is subject matter that appellant regards as its invention.

None of the limitations (iv), (v), or (vi), as identified above, are disclosed by Rosenberg.

Notwithstanding allegation number (iv) above, the Examiner admits that Rosenberg does not explicitly disclose a first device for performing a first skin interaction technique wherein:

> the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein:
> (a) …; and
> (b) said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.

The Examiner alleges, however, that Pugh provides this missing teaching. In particular, the Examiner alleges that Pugh teaches:

(a) a first device (sensors) for performing a first skin-interaction technique (para 0012) that is used in conjunction with a simulated vascular-access procedure (para 0062);

(b) wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion;

(c) wherein the first skin-interaction technique is performed on the pseudo skin at a first skin-interaction region (Fig. 3 and paras. 0041 and 0042); and

(d) wherein the insertion region is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.

Appellant disagrees with all of these allegations.

As to allegations (a) and (b), the "first device" (sensors) of Pugh is not a device for performing a first skin-interaction technique that is used in conjunction with a simulated *vascular-access* procedure. Furthermore, although Pugh discloses "palpation" of a blood vessel, in the context discussed, it is neither a "skin-interaction technique" nor performed in conjunction with a simulated "vascular-access procedure." These points are discussed further below.

The Examiner cites to para. [0062] of Pugh to support her contention that Pugh discloses a device for performing a skin-interaction technique used in conjunction with a *simulated vascular-access procedure.*

Paragraph [0062] of Pugh discloses that many surgical procedures require the surgeon to feel (palpate) internal organs or internal body surfaces during surgery. Pugh discloses the example of a surgery for removing a retro-peritoneal tumor, which:

> require[s] a surgeon to directly palpate the location and extent of the tumor to know the difference between the tumor and normal tissue. By hand, the surgeon can feel where the solid tumor ends and a major blood vessel begins for example.

(Para. 0062 at lines 14+, emphasis added. *See also*, para. 0013: "In other cases, the abnormality in the organ can not be palpated through the abdominal wall but … which may be palpable once the abdomen is opened for surgical assessment and treatment.")

Palpation, as practiced during surgery to discriminate between a tumor and blood vessel, is not a "skin-interaction technique." The "palpation" being referenced in Pugh occurs *within* the body; that is, directly on the tumor and blood vessel. As such, it is not properly termed a *skin* interaction technique, since there is no interaction with "skin." This is to be contrasted with palpation as performed in the context of a vascular-access procedure, in which the palpation is performed *outside* of the body, on the skin of a patient, such as to locate a vein that is not directly observable.

In fact, Pugh has nothing to do with "vascular-access procedures." The website for the Radiological Society of North America (RSNA) provides a concise definition of the phrase "vascular access procedure:"

> A vascular access procedure involves the insertion of a flexible thin plastic tube, or catheter, into a blood vessel to provide a painless way of drawing

> blood or delivering drugs and into a patient's bloodstream over a period of weeks, months or even years.

(*See* http://www.radiologyinfo.org/en/pdf/vasc_access.pdf)

This definition is consistent with the "Background" section of appellant's specification, wherein exemplary vascular-access procedures are identified as IV insertion, central venous-line placement, peripherally-inserted central catheter, *etc*.

Palpation, as performed in conjunction with a vascular access procedure, has a different purpose and is performed using a different technique than intra-body-cavity palpation as described in Pugh. In that regard, appellant points out that the "first device" recited in claim 1 is defined *functionally*; the function that the first device performs is: "a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure." Devices suitable for performing that function are disclosed and defined in applicant's co-pending U.S. Patent Application S.N. 10/807,017, which is incorporated by reference in the case on appeal. *See*, para. [0042] of the case on appeal, wherein U.S. Patent Application S.N. 10/807,017 is specifically referenced as a source for more information about "palpation module **222** and skin-stretch module **224**," for performing skin-interaction techniques.

At paragraph [0058]-[0059] of U.S. Pat. Appl. No. 10/807,017, it is disclosed that:

> Palpation module **222** advantageously provides the following *functionality*:
>
> - Enables a user to search for a vein.
> - Provides haptic feedback to user.
> - Provides indirect measurement of palpation force.
> - Enables a user to occlude a vein.
>
> Evaluation of vascular-access procedures and anatomy led to the recognition that, in addition to the listed functionality, it is desirable for palpation module **222** to exhibit certain *characteristics*, as described below:
>
> - The vein should be felt but not "seen."
> - A vein should not be felt when it's not present.
> - If pressed hard, the vein should "disappear."
> - The vein should have a "spongy" or "yielding" feel when palpated.
> - Vein stiffness should be controllable.

At paragraph [0065] of U.S. Pat. Appl. No. 10/807,017, it is disclosed that:

> Palpation assembly **436** depicted in FIGs. 4A – 4E, which is an illustrative physical realization of palpation module **222**, possesses all of the functionality and exhibits all the characteristics listed above. But it is understood that palpation assembly **436** is but one physical realization of palpation module **222**; others are contemplated. And for some applications, such as those in which cost is a consideration, it might be desirable or otherwise necessary to implement palpation module **222** such that it provides only some (one or more) of the functions *and* exhibits only some (one or more) of the characteristics listed above.

Thus, for a device to be suitable as a palpation assembly for use in conjunction with a vascular access procedure, it should be capable of providing at least one function listed above and of exhibiting at least one characteristic listed above.

The sensors of Pugh, which the Examiner alleges satisfies limitation of "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure" does not provide any of the defined characteristics.

Bottom line:

- The sensors of Pugh simply measure the palpation pressure that is applied by a practitioner during palpation of an *organ*;
- Pugh does not disclose the use of *any* device to facilitate palpation of blood vessels;
- Pugh does not disclose any device for performing palpation or occlusion in conjunction with a vascular access procedure.

Regarding allegation (c), Pugh does not disclose that the first skin-interaction technique is performed on the pseudo skin at a first skin-interaction region. Pugh does disclose palpating *organs* by pressing on pseudo skin and using a sensor to evaluate palpation pressure, which is disclosed in Pugh at paras. [0041]-[0042] and elsewhere. But, as previously discussed, there is no teaching or suggestion in Pugh to perform a skin-interaction technique used in conjunction with a vascular-access procedure. That is, Pugh provides no teaching pertaining to palpating/occluding a blood vessel by pressing on the surface of the (pseudo) skin at a first skin-interaction region.

As to allegation (d) concerning the relative locations of the "insertion region" and the "skin interaction region" when in use, the usefulness of a simulator, such as appellant's claimed vascular-access simulation system, is very dependent upon ergonomic considerations and

the extent to which the simulator mimics the experience of conducting the actual procedure that is being simulated. As noted in the specification at paragraphs [0006]+, prior-art simulators did a generally poor job in simulating actual conditions, as a consequence of poor ergonomics and other factors. One of the focuses of appellant's vascular-access simulation system, and the claims on appeal in particular, are the ergonomic aspects of the simulator's design.

The Examiner effectively ignores the limitation pertaining to the relative locations of the specific regions, stating, at page 5 of her *Official Action*, that "One region would be closer to a user than another region, depending upon the location of the user with respect to the apparatus." Indeed it would.

When using appellant's device as intended, the relative positions of the user, the insertion region, and first skin interaction region will be correct vis-à-vis the actual procedure. See, for example, FIGs. 3 and 8. With the device oriented as shown in FIG. 8, the insertion region (334) is closer to the user than the first skin-interaction region (331) for practicing palpation or occlusion. This is the orientation that would be used if someone *were performing the actual procedure on a live patient*. There is no teaching in the cited art to arrange a simulator in this manner.

Therefore, it is appellant's contention that Pugh does not disclose limitations (a)-(d).

In summary, neither Rosenberg nor Pugh disclose the following limitations:

- a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure;
- wherein the first skin-interaction technique is performed on the pseudo skin at a first skin-interaction region of the pseudo skin;
- wherein said receiver and said first device are disposed beneath said pseudo skin;
- wherein said receiver and said first device are covered by said pseudo skin;
- wherein said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.

Since the combination of Rosenberg and Pugh do not disclose or otherwise suggest all the limitations of claim 1, this combination cannot be said to obviate claim 1 under 35 USC §103. As a consequence, the Board is requested to reverse the Examiner's rejection of claim 1 over the combination of Rosenberg and Pugh.

It is not necessary to address in detail the issue of the appropriateness of combining the teachings of the Rosenberg and Pugh since the combination does not disclose or suggest many of the limitations of claim 1. In this regard, appellant simply notes that it would be inappropriate to combine the teachings of a reference that is directed to practicing hand manipulation skills (Pugh) with those of a reference that is directed to practicing the use of a surgeon's tool, *etc*. (Rosenberg). The structure and layout of the devices that are used in these two references are necessarily quite different. One cannot simply suggest that because something is known or used in one context that it is therefore appropriate for use in the other context.

Claim 35. Claim 35 recites recites an apparatus comprising:

> a pseudo skin;
> a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, including at least one mechanism for performing a non-invasive skin-interaction technique that is performed on said pseudo skin, wherein said plurality of mechanisms are disposed under said pseudo skin and are covered by said pseudo skin; and
> a housing, wherein said housing contains said plurality of mechanisms.

The Examiner alleges, at page 5 of her *Official Action*, that Rosenberg teaches:

(i) a pseudo skin (barrier (22));
(ii) a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure (mechanical apparatus 25 and trocar (24);
(iii) wherein the plurality of mechanisms are disposed under the skin;
(iv) wherein the plurality of mechanisms are covered by said pseudo skin;
(v) a housing, wherein said housing contains said plurality of mechanisms.

Appellant disagrees with at least allegations (iii)-(v). As previously discussed, Rosenberg does not disclose, either in the figures or the disclosure, that a plurality of mechanisms are disposed under barrier (22) or covered by barrier (22). Furthermore, Rosenberg does not teach or suggest that a housing contains the plurality of mechanisms. In fact, none of the drawings indicate the presence of a housing, nor does the disclosure make any mention of a housing. The barrier is not a housing.

The Examiner admits that Rosenberg doesn't disclose that at least one of the plurality of mechanisms for simulating a vascular-access procedure is a mechanism for performing a

non-invasive skin-interaction technique that is performed on said pseudo skin. The Examiner alleges, however, that Pugh teaches such a mechanism, referencing para. [0012].

As previously discussed, Pugh does not teach any mechanism that simulates a vascular-access procedure and that performs a skin-interaction technique, non-invasive or otherwise. (Note that claim 35 requires that the mechanism for performing the non-invasive skin-interaction procedure is one of the mechanisms for simulating a vascular access procedure.) Although Pugh teaches palpation of the skin for conducting abdominal exams, soft tissue exams, *etc*., Pugh does not teach or disclose a mechanism for performing any skin-interaction technique, including palpation, as it pertains to a vascular access procedure.

Neither Rosenberg nor Pugh, nor the combination thereof discloses:

- a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, including at least one mechanism for performing a non-invasive skin-interaction technique that is performed on said pseudo skin;
- a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure are disposed under said pseudo skin;
- a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure are covered by said pseudo skin; and
- a housing that contains the plurality of mechanisms with which a user interacts for simulating a vascular-access procedure.

Since the combination of Rosenberg and Pugh do not disclose or otherwise suggest all the limitations of claim 35, the combination cannot be said to obviate that claim. As a consequence, the Board is requested to reverse the Examiner's rejection of claim 35 under 35 USC §103 over the combination of Rosenberg and Pugh.

Claims 38-40. Claims 38-40 are dependent on claim 35. Since claim 35 has been shown to be allowable over the combination of Rosenberg and Pugh, claims 38-40 are likewise allowable on that basis. Furthermore, it is noted that at least claim 40 contains additional limitations not disclosed or suggested by either Rosenberg, Pugh, or the combination thereof.

Claim 40 recites:

> said plurality of mechanisms comprise discrete devices, wherein a first of said devices is for enabling a user to perform a skin-stretch technique, a second of said devices is for receiving a needle or catheter or both, and a

> third of said devices is for enabling a user to perform at least one of either a palpation technique or an occlusion technique.

Neither Rosenberg nor Pugh nor the combination thereof disclose or suggest a device that enables a user to perform "a skin-stretch technique," which is the third of the three skin interaction techniques that appellant's simulator is capable of enabling a user to practice. As a consequence, the Board is requested to reverse the Examiner's rejection of claims 38-40 under 35 USC §103 over the combination of Rosenberg and Pugh.

***Ground* 3.** The Examiner alleges that claims 4-7 and 13-24 are unpatentable under 35 USC 103(a) over the combination of Rosenberg and Pugh, and further in view of U.S. Pat. No. 6,470,302 to Cunningham *et al*.

The Cunningham reference is directly relevant to appellant's claimed invention. In fact, that patent as well as a device consistent therewith were extensively studied in the development of appellant's claimed simulator. In fact, identifying the many shortcomings of the Cunningham device was the starting point for the development of appellant's simulator.

Claim 4 recites:

> The apparatus of claim 1 further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin.

Claim 5 recites:

> The apparatus of claim 4 wherein:
> said second skin-interaction technique comprises skin stretching; and
> said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin when said user is using said apparatus.

The Examiner admits that the combination of Rosenberg and Pugh does not disclose a "second device for performing a second skin-interaction technique on the pseudo skin at a second skin interaction region of the pseudo skin" nor that the "second skin-interaction technique comprises skin stretching." But the Examiner asserts that Cunningham discloses

a second skin-interaction technique, and also teaches that the technique is "skin stretching."

As already discussed, neither Rosenberg nor Pugh disclose "a first skin interaction technique that is used in conjunction with a vascular-access procedure." That being the case, Cunningham cannot disclose a *second* such technique. Cunningham, in fact, discloses a rudimentary skin stretching mechanism, as depicted in FIG. 3 (skin traction mechanism (36) and casing (127) and FIG. 7 (showing the details of the mechanism). But this is the only skin-interaction technique that Cunningham teaches; it provides no mechanisms for practicing palpation or occlusion. And that omission in and of itself is telling. Palpation and occlusion were not "discovered" after Cunningham filed his patent application. That fact Cunningham, which is directed to a vascular access simulation system, did not include mechanisms for practicing palpation or occlusion, is relevant to the determination of the novelty and non-obvious of a claimed simulator, such as appellant's, that includes such features.

Since Rosenberg and Pugh do not teach "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure" and since Cunningham only discloses a single skin-interaction technique (skin stretch), the combination of these references do not disclose all the limitations of claims 4 or 5.

Claim 6 recites:

> The apparatus of claim 1 further comprising a housing, wherein**:**
> (a) said receiver and said first device are contained within said housing;
> (b) said pseudo skin is substantially co-extensive with a surface of said housing;
> (c) said housing has an anterior portion and a posterior portion;
> (d) in use, said anterior portion is proximal to a user; and
> (e) said posterior portion is distal to said user.

Claim 7 recites:

> The apparatus of claim 6 wherein an uppermost surface of said housing is no more than about 5 inches above a lowermost surface thereof.

As already discussed, the combination of Rosenberg and Pugh does not disclose the claimed "first device" (for performing a first skin-interaction technique that is used in conjunction

with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion) nor does the combination of these references disclose that the receiver and non-existent first device are "contained in said housing."

The Examiner argues that the "barrier (22)" of Rosenberg is a housing. Yet, barrier (22) houses nothing; it is a partition. Furthermore, the Examiner alleges that the pseudo skin is substantially co-extensive with a surface of said housing, as per limitation (b) of claim 6. Words in a claim are understood to have meaning and different words are understood to have different meaning. "Pseudo skin" and "housing" are not the words and they are not the same thing; appellant's specification or the dictionary provide adequate proof of that, if any such proof is required.

But Cunningham does disclose a housing (*see*, FIG. 3, case (32)) that houses at least a portion of a catheter unit assembly (34) (*see*, FIG. 4). The catheter needle assembly (47) couples to the catheter unit assembly. Movement of the catheter needle assembly by a user is intended to simulate movement of a catheter/needle. Various mechanisms that are a part of the catheter unit assembly (34) track this movement and provide haptic feedback to the user.

As previously indicated, the only device disclosed in Cunningham that pertains to a skin-interaction procedure is skin traction mechanism (36). Regarding claim 6, the skin traction mechanism (36) does not meet the limitations of "the first device" because it is does not enable a user to perform palpation or occlusion (as required per base claim 1). Furthermore, skin traction mechanism (36) resides in its own casing (127). Claim 6 requires both the "receiver" and the "first device" to reside within the housing, which in the Cunningham is "case (32)." Clearly, the skin traction mechanism does not reside in case (32).

Regarding claim 7, neither Rosenberg nor Pugh disclose a "housing." Cunningham does. Although the reference itself is silent on size, as previously noted, appellant was in possession of the device disclose in Cunningham. The housing was bigger than five inches, top to bottom.

Claims 13 adds the limitation, to claim 6, of a second device for performing a second skin-interaction technique, wherein the second device is disposed beneath and covered by the pseudo skin. This claim thus recites two devices for performing different skin-interaction

techniques, and wherein both are within the housing (since there are disposed beneath and covered by the pseudo skin). The combination of Rosenberg, Pugh, and Cunningham does not disclose these limitations.

Claims 14-19 are all dependent on claim 13. Claim 14 recites that the second skin-interaction technique is skin stretch. Claims 15-19 pertain to ergonomic considerations, reciting limitations that pertain to orientation/positioning of elements of the apparatus relative to one another. These limitations are not disclose or suggested by the cited art.

Since the combination of Rosenberg, Pugh, and Cunningham does not teach or disclose all of the limitations of each of claims 4-7, 13-19, and 21-24, those claims are allowable over those references. As a consequence, the Board is requested to reverse the Examiner's rejection of claims 4-7, 13-19, and 21-24 under 35 USC §103 over the combination of Rosenberg, Pugh, and Cunningham.

***GROUND* 4.** The Examiner alleges that claim 25 is unpatentable under 35 USC 103(a) over Cunningham *et al*. in view of Rosenberg.

Claim 25 recites an apparatus comprising:

> a housing, wherein said housing has an opening in an uppermost surface thereof;
>
> pseudo skin, wherein said pseudo skin covers said opening;
>
> an end effector, wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure; and
>
> a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin, and wherein said plurality of mechanisms include:
>
> (a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin; and
>
> (b) a second mechanism for receiving said end effector.

The Examiner alleges that Cunningham discloses:

(a) housing (30);
(b) housing has an opening in an uppermost surface thereof;
(c) pseudo skin;
(d) the pseudo skin covers the opening in the housing;

(e) the end effector is inserted into said housing through said pseudo skin during the performance of a vascular access procedure;
(f) a plurality of mechanisms contained completely within the housing;
(g) the plurality of mechanisms are covered by said pseudo skin; and
(h) a first mechanism of the plurality simulates a skin-stretch technique.

The Examiner further alleges that Cunningham does not disclose a second mechanism for receiving said end effector, but Rosenberg does (mechanism (25) for receiving end effector (18)).

Appellant agrees that Cunningham discloses a housing, which is case (32), as depicted in Fig. 3. Appellant agrees that the housing has an opening in an uppermost surface thereof (close enough, anyway). This opening is not referenced, but the back end of catheter needle assembly (47) and the receiving shaft (44), as depicted in Fig. 4, can be seen emerging from that opening. Appellant agrees that Cunningham discloses a pseudo skin, which the Examiner correctly identifies as belt (108) of skin traction mechanism (36) (*see*, Figs. 3 and 7). And appellant agrees that Cunningham discloses a skin stretch mechanism, which is skin traction mechanism (36).

Appellant, however, disagrees with allegations (d)-(g).

Allegation (d): As seen in Fig. 3, the pseudo skin—belt (108)—does NOT cover the opening in case (32). The belt "covers" the opening of casing (127).

Allegation (e): As will be appreciated from Fig. 3, when practicing a vascular access procedure using Cunningham's simulator, the end effector (the catheter needle assembly (47)) is NOT inserted into the housing through the pseudo skin (belt (108)).

In fact, although it is not particularly clear from the specification, catheter needle assembly (47) is never fully withdrawn from receiving shaft (44). This can be better appreciated with reference to Fig. 5A, wherein if the needle handle (48) were pulled far enough to the "right," (in the Figure), the needle (protruding from needle shaft (72)), would dislodge from catheter tube (91). Since the entrance to the catheter tube (91) is spaced from the o-ring (76), re-insertion of the needle into catheter tube would be very problematic. Thus, a user does not actually insert the end effector into the housing; it is already inserted *before* the simulation begins. And that is how the commercial version of that simulator actually works.

Allegation (f): The plurality of mechanisms, which include a first mechanism for performing the skin stretch (skin traction mechanism (36)), and the second mechanism for receiving the end effector (receiving shaft (44)) are NOT completely contained in the housing. A portion of receiving shaft (44) extends beyond the housing. And no portion of the skin stretch mechanism is within the housing.

Allegation (g): The second mechanism for receiving the end effector (shaft (44)) is not covered by the pseudo skin.

Appellant also disagrees with the Examiner's allegation that Cunningham does not disclose a second mechanism for receiving said end effector. In fact, Cunningham does disclose such a mechanism; it is receiving shaft (44).

The combination of Cunningham and Rosenberg does not disclose or suggest all the limitations that are recited in claim 25. As a consequence, the Board is requested to reverse the Examiner's rejection of claim 25 under 35 USC §103 over the combination of Cunningham and Rosenberg.

***GROUND* 5.** The Examiner alleged that claims 28 and 33 are unpatentable under 35 USC 103(a) over Cunningham *et al*. and Rosenberg, and further in view of Pugh.

Claim 28 recites:

> The apparatus of claim 25 wherein said mechanisms includes a third mechanism for simulating at least one of a palpation or an occlusion technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin, and wherein said end effector is at least one of either a needle or a catheter.

Claim 28 recites a third mechanism for simulating at least one of palpation or an occlusion technique that is used in conjunction with a simulated vascular-access procedure, in addition to other limitations. As already discussed neither Cunningham, Rosenberg or Pugh disclose a mechanism for simulating a palpation technique or an occlusion technique that is used in conjunction with a simulated vascular-access procedure. As a consequence, claim 28 is not obvious in view of these references.

Claim 33 recites:

> The apparatus of claim 28 wherein said housing has an anterior end and a posterior end, wherein in use, said anterior end is proximal to a user, and wherein a portion of said second mechanism is flanked by said first mechanism proximal to said anterior end and said third mechanism proximal to said posterior end.

Claim 33 recites the positioning of the three mechanisms (skin stretch, receiver, and palpation/occlusion) relative to one another within the housing. This arrangement is not

taught or suggested by the Cunningham, Rosenberg, or Pugh and, therefore, claim 33 is not obvious in view of these references.

The Board is therefore requested to reverse the Examiner's rejection of claims 28 and 33 under 35 USC §103 over the combination of Cunningham, Rosenberg, and Pugh.

***GROUND* 6.** The Examiner alleged that claim 34 was unpatentable under 35 USC 103(a) over Cunningham *et al*. and Rosenberg, further in view of Pugh.

Claim 34 recites:

> The apparatus of claim 28 wherein:
> a user interacts with said first mechanism at a first site on said pseudo skin;
> said user interacts with said second mechanism at a second site on said pseudo skin;
> said user interacts with said third mechanism at a third site on said pseudo skin; and
> locations of each of said first site, second site, and third site on said pseudo skin correspond to locations of said first mechanism, second mechanism, and third mechanism, respectively, within said housing.

The first mechanism is for performing simulated skin stretch, the second mechanism is a receiver for receiving the catheter or needle, and the third mechanism is for performing simulated palpation/occlusion.

In the apparatus of Cunningham, a simulated skin stretch (first mechanism) is performed when a user interacts with the pseudo skin (belt (108)). The user's interaction with the receiver (shaft (44)) (second mechanism) does not occur at any site on the pseudo skin. Cunningham provides no provision for palpation/occlusion (third mechanism).

In the apparatus of Rosenberg, no provision for simulating a skin stretch (first mechanism) or palpation/occlusion (third mechanism) is provided. As to the second mechanism, the user does interact with the receiver (trocar (24)) at a site on the pseudo skin. That said, claim 25, on which claim 34 depends, recites that the end effector "is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure."

In Rosenberg, the end effector is NOT inserted through the pseudo skin during the performance of the simulated vascular-access procedure. (And there is no "housing" disclosed.) As noted at col. 5, line 60 – col. 6, line 3:

> The present invention is concerned with tracking the movement of the shaft portion (28) in three-dimensional space, where the movement has been constrained such that the shaft portion (28) has only three or four free degrees of freedom. This is a good simulation of the use of a laparoscopic tool (18) in that once it is inserted into a trocar (24) and through the gimbal apparatus (25), it is limited to about four degrees of freedom. More particularly, the shaft (28) is constrained at some point of along its length such that it can move with four degrees of freedom within the patient's body.

(Emphasis added.)

As indicated by this passage, the laparoscopic (18) is inserted through the trocar (24) and into the gimbal apparatus (25), to limit motion to four degrees of freedom, before the simulated vascular access procedure begins. This is typical for this type of system due to the difficulty in decoupling an end effector from its force feedback system. The Cunningham simulator suffers from the same drawback, as noted at para. [0009] of U.S. Pat. Application S.N. 10/807,047, which is incorporated by reference into the case on appeal:

> A second shortcoming of the '302 is that the end effector (*i.e.*, the catheter unit assembly) is permanently coupled to the force-feedback system. Although not atypical for this type of system (*i.e.*, haptics devices) due to the difficulty of de-coupling an end effector from its force-feedback system, this is very undesirable because to truly mimic most "actual" systems, de-coupling is necessary.

Indeed, in an actual vascular access procedure, the end effector—the needle/catheter—is not inserted into the "receiver" (a patient's arm, for example) until the procedure actually begins. In applicant's claimed invention, such decoupling is achieved, which is described in detail in related U.S. patent applications that are incorporated by reference into the case on appeal.

In the apparatus of Pugh, no provision for simulating a skin stretch (first mechanism) or palpation/occlusion (third mechanism) in conjunction with a vascular-access procedure is provided. Furthermore, to the extent that Pugh mentions palpating a tumor to distinguish it from a blood vessel, this is done when the "body cavity" is open, as previously discussed;

palpation is not performed on pseudo skin (to locate an invisible underlying vessel). Furthermore, Pugh provides no disclosure of a second mechanism; that is, the user does not interact with the receiver at a site on any pseudo skin.

As a consequence, there is no support for the Examiner's contention that the combination of Cunningham, Rosenberg, and Pugh teach interacting with the first, second, and third mechanisms at respective first, second, and third sites on pseudo skin. Nor is there any disclosure or suggestion in the prior art that the locations of those sites should correspond to the relative position of the mechanisms within the housing.

Claim 34 is allowable based on its dependence on claim 28, which has been shown to be patentable over the same art. Furthermore, since many of the limitations of claim 34 are not taught or suggested by the combination of Cunningham, Rosenberg, and Pugh, that claim is not obvious in view of those references. The Board is therefore requested to reverse the Examiner's rejection of claim 34 under 35 USC §103 over the combination of Cunningham, Rosenberg, and Pugh.

GROUND 7. The Examiner alleged that claims 36 and 37 are unpatentable under 35 USC 103(a) over Rosenberg. These claims are dependent on claim 35, which has been shown to be allowable over Rosenberg and Pugh. Therefore, claims 36 and 37 are allowable over Rosenberg.

The Board is therefore requested to reverse the Examiner's rejection of claims 36 and 37 under 35 USC §103 over Rosenberg.

CONCLUSION

The appellant has demonstrated that the logic underlying the Examiner's rejections is untenable, and, therefore, that the rejections are not sustainable. For this reason, the appellant respectfully requests the Board of Appeals to reverse the decision of the Examiner as provided for in 37 C.F.R. 41.50(a).

Respectfully,
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Claims Appendix

1. (Previously Presented) An apparatus comprising:

pseudo skin;

a receiver, wherein said receiver receives an end effector through an insertion region in said pseudo skin; and

a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein:

(a) said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin; and

(b) said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.

2. – 3. (Canceled)

4. (Previously Presented) The apparatus of claim 1 further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin.

5. (Previously Presented) The apparatus of claim 4 wherein:

said second skin-interaction technique comprises skin stretching; and

said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin when said user is using said apparatus.

6. (Previously Presented) The apparatus of claim 1 further comprising a housing, wherein**:**

(a) said receiver and said first device are contained within said housing;

(b) said pseudo skin is substantially co-extensive with a surface of said housing;

(c) said housing has an anterior portion and a posterior portion;

(d) in use, said anterior portion is proximal to a user; and

(e) said posterior portion is distal to said user.

7. (Previously Presented) The apparatus of claim 6 wherein an uppermost surface of said housing is no more than about 5 inches above a lowermost surface thereof.

8. – 12. (Canceled)

13. (Previously Presented) The apparatus of claim 6 further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin.

14. (Previously Presented) The apparatus of claim 13 wherein said second skin-interaction technique comprises skin-stretch.

15. (Original) The apparatus of claim 14 wherein at least some portion of said second device is closer to said anterior portion of said housing than said first device.

16. (Original) The apparatus of claim 14 wherein at least some portion of said second device is closer to said anterior portion of said housing than said first end of said receiver.

17. (Original) The apparatus of claim 14 wherein said first end of said receiver is closer to said anterior portion of said housing than said first device.

18. (Previously Presented) The apparatus of claim 14 wherein an upper-most surface of said first device extends a greater distance above a lowermost surface of said housing than said first end of said receiver.

19. (Previously Presented) The apparatus of claim 14 wherein an upper-most surface of said first device extends further above a lowermost surface of said housing than an upper-most surface of said second device.

20. (Canceled)

21. (Previously Presented) The apparatus of claim 6 further comprising an electronics/communications interface, wherein:

said electronics/communications interface receives signals from sensors that are associated with at least one of said first device or said receiver; and

said electronics/communications interface is disposed beneath said pseudo skin and is covered by said pseudo skin.

22. (Original) The apparatus of claim 21 wherein said electronics/communications interface is closer to said posterior portion of said housing than said first device.

23. (Original) The apparatus of claim 21 wherein said electronics/communications interface is closer to said posterior portion of said housing than said receiver.

24. (Original) The apparatus of claim 21 wherein said electronics/communications interface comprises a printed circuit board, and further wherein a major surface of said printed circuit board is disposed orthogonal to an uppermost surface of said first device.

25. (Previously Presented) An apparatus comprising:

a housing, wherein said housing has an opening in an uppermost surface thereof;

pseudo skin, wherein said pseudo skin covers said opening;

an end effector, wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure; and

a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin, and wherein said plurality of mechanisms include:

(a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin; and

(b) a second mechanism for receiving said end effector.

26. – 27. (Canceled)

28. (Previously Presented) The apparatus of claim 25 wherein said mechanisms includes a third mechanism for simulating at least one of a palpation or an occlusion technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin, and wherein said end effector is at least one of either a needle or a catheter.

29. – 32. (Canceled)

33. (Previously Presented) The apparatus of claim 28 wherein said housing has an anterior end and a posterior end, wherein in use, said anterior end is proximal to a user, and wherein a portion of said second mechanism is flanked by said first mechanism proximal to said anterior end and said third mechanism proximal to said posterior end.

34. (Previously Presented) The apparatus of claim 28 wherein:

a user interacts with said first mechanism at a first site on said pseudo skin;

said user interacts with said second mechanism at a second site on said pseudo skin;

said user interacts with said third mechanism at a third site on said pseudo skin; and

locations of each of said first site, second site, and third site on said pseudo skin correspond to locations of said first mechanism, second mechanism, and third mechanism, respectively, within said housing.

35. (Previously Presented) An apparatus comprising:

a pseudo skin;

a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, including at least one mechanism for performing a non-invasive skin-interaction technique that is performed on said pseudo skin, wherein said plurality of mechanisms are disposed under said pseudo skin and are covered by said pseudo skin; and

a housing, wherein said housing contains said plurality of mechanisms.

36. (Original) The apparatus of claim 35 wherein said housing is no more than about 5 inches in height.

37. (Original) The apparatus of claim 35 wherein said housing is no more than about 4 inches in height.

38. (Original) The apparatus of claim 35 wherein at least one of either a needle or catheter is disposed outside of said housing until inserted therein during a simulated vascular-access procedure.

39. (Original) The apparatus of claim 35 further comprising a data processing system, wherein said data processing system receives signals from sensors that are associated with said plurality of mechanisms.

40. (Original) The apparatus of claim 35 wherein said plurality of mechanisms comprise discrete devices, wherein a first of said devices is for enabling a user to perform a skin-stretch technique, a second of said devices is for receiving a needle or catheter or both, and a third of said devices is for enabling a user to perform at least one of either a palpation technique or an occlusion technique.

Evidence Appendix

There is no evidence submitted pursuant to 37 CFR §§ 1.130, 1.131, or1.132.

Related Proceedings Appendix

There are no related proceedings.